IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Burrows et al. Art Unit : 1626
Serial No. : 10/527,349 Examiner : Yong Liang Chu
Filed : March 10, 2005
Title : SULPHONAMIDE DERIVATIVES AND THEIR USE AS TACE INHIBITORS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

This paper is responsive to the Restriction Requirement mailed on January 17, 2006. Applicants respectfully traverse the Office's grounds for restriction of claims 1-12 and 15-18 of the present application. This is discussed in more detail below.

The Office asserts that the present claims are directed to more than one invention, and that these inventions "are not so linked as to form a single inventive concept under PCT Rule 13.1" (Restriction Requirement, page 3).

Presently, the Office is requiring that Applicants select among eight restriction groups (Groups I-VIII). The Office has restricted the composition of matter claims into four groups (Groups I, II, III, and IV). The remaining four groups include the method of use (Group V) and method of making (Groups VI-VIII) claims. As will be discussed in more detail below, all claims, regardless of whether they are compound, pharmaceutical composition, method of making, or method of using, possess unity. All require the special technical feature (See PCT Rule 13.2) of a hydantoin ring (z =N) (or hydantoin-like ring, z = O, S)) tethered to a phenolic ether.

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Applicants begin with a discussion of Groups I-IV.

Each of Groups I-IV differs with respect to the identity of variables "n" (which determines whether the methylene group -C(R^5)(R^6)- is present or absent in formula (IA)) and "V" (a linker connecting the phenyl ring and "W" in formula (IA)) in claim 1. The specific values for "n" and "V" in each of Groups I-IV are summarized in the Table below:

Group	n	V
I	0	NR^{15}
II	1	NR^{15}
III	0	SO_2
IV	1	SO_2

Applicants respectfully reconsideration of the restriction groupings set forth above for the following reasons.

First, there is no basis for restricting claims 1-12 and 16 into groups in which "V" is separately NR^{15}. The present claims are **not** drawn to compounds in which "V" is NR^{15} (amino). Claim 1 is drawn to compounds in which "V" in formula (IA) is $NR^{15}SO_2$, i.e., a sulfonamide linkage of which NR^{15} is an intergral, non-separable part. Similarly, claim 2 is drawn to compounds in which "V" in formula (IB) is SO_2 or CO, but not NR^{15}. Applicants therefore respectfully request that the Office's restriction of claims 1-12 on the basis of "V" be reconsidered and withdrawn.

Further, the Markush groups recited in the present claims embrace chemical compound alternatives that share a significant structural element, regardless of the identity of variable "n." More specifically, the compound alternatives of the claims all include a hydantoin or hydantoin-like ring tethered to a phenolic ether *via* a tethering moiety that includes a saturated carbon atom (i.e., (-C(R^3)(R^4)-) and an oxo-substituted atom (i.e., V). This structural commonality exists among all of the compound alternatives of claim 1 regardless of whether "n" is 0 or 1. As mentioned elsewhere, "n" only determines whether a second carbon atom (i.e., -C(R^5)(R^6)-) is present in the tethering moiety. As such, the Markush groupings recited in the present claims

embrace chemical compound alternatives that share a significant structural element and therefore at least meet prong B(1) of the PCT unity of invention criteria for Markush practice (see MPEP § 1850).

As such, unity of invention is met with respect to claims 1-12 and 16.

Applicants now turn to Groups V-VIII.

Group V is a method of treating an inflammatory disease, which includes administering a compound of claim 1. Groups VI-VIII are methods of making the compounds of claim 1. Each of Groups V-VIII require the same special technical feature found in the composition of matter claims (i.e., Groups I-IV, claims 1-12 and 16): a hydantoin or hydantoin-like ring tethered to a phenolic ether *via* a tethering moiety that includes a saturated carbon atom (i.e., (-C(R^3)(R^4)-) and an oxo-substituted atom (i.e., "V").

In addition, 37 C.F.R. 1.475(b)(3) provides as follows:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: ... (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

The claimed processes in Groups V and VI-VIII are clearly specifically adapted to using and making, respectively, the compounds of claim 1: the compounds of claim 1 are either a required element or the required result of claims 15 and 17-18, respectively. Applicants also note that the Office must follow PCT Rule 13 and not national practice in these determinations. Thus, even if the Groups were properly restricted under national practice (and Applicants do not concede that to be the case), PCT Rule 13 requires, in this case, rejoinder of the Groups. See MPEP § 1850:

> Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of

claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111.

Again, the MPEP requires the Office "should not raise objection of lack of unity of the invention merely because the inventions claimed are classified in separate classification groups." (MPEP § 1850).

Thus, unity of invention is met with respect to claims 15 and 17-18. Moreover, Groups V-VIII should be rejoined with Groups I-IV for the reasons provided above.

As argued above, Applicants submit that Groups I-VIII should be rejoined, but as required Applicants elect Group I, drawn to compounds of formula (IA) in which **n is 0**, but **V is $NR^{15}SO_2$** and not NR^{15}, with traverse. Commensurate with the election of Group III, Applicants elect for search purposes only the species compound, N-{4-[(2-methylquinolin-4-yl)methoxy]phenyl}-2,4-dioxo-1,3-diazaspiro[4.4]nonane-6-sulphonamide, which is disclosed in the Specification as Example 8A, at Page 64, lines 5-25. The elected species is readable on claims 1, 3, 4, 5, 6, and 15-18.

In the event that the Examiner maintains the present restriction, Applicants respectfully request that claim 15, a method of treating an inflammatory disease be rejoined with compound and composition claims 1-12 and 16, respectively once claims 1-12 are allowed. As required by the rejoinder procedure, claim 15 depends from claim 1 and is therefore eligible for rejoinder with product and composition claims 1-12 and 16 once the Examiner deems that claims 1-12 and 16 are in condition for allowance.

If this election is not acceptable to the Examiner, Applicants respectfully request that the Examiner contact their undersigned representative to discuss the restriction groups or this election. Applicants thank the Examiner in advance for this courtesy.

Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No.: 06275-445US1.

Respectfully submitted,

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